



DOCKET NO.: C1039.70058US00

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis et al.  
Serial No.: 10/023,909  
Confirmation No.: 8458  
Filed: December 18, 2001  
For: USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CPG  
DINUCLEOTIDE AS AN ADJUVANT

Examiner: Jeffery S. Parkin  
Art Unit: 1648

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16<sup>th</sup> day of November, 2004.

  
Kristin J. Ketelhut

**MAIL STOP AMENDMENT**

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

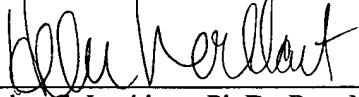
Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Davis et al., Applicant*

  
By: Helen C. Lockhart, Ph.D., Reg. No.: 39,248  
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11/19/2004 RFEKADU1 00000019 10023903

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Docket No.: C1039.70058US00

Date: November 16, 2004

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Kristin J. Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF**  
**DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references. The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|-------------------|-------------------|--------------------|--------------------|
| *C1037.70013US01  | 10/831,778        | April 23, 2004     | Bratzler et al.    |
| *C1037.70039US01  | 10/816,220        | April 1, 2004      | McCluskie et al.   |
| *C1037.70050US01  | 10/952,254        | September 27, 2004 | Uhlmann et al.     |
| *C1039.70020US01  | 10/921,086        | August 18, 2004    | Krieg et al.       |
| *C1039.70035US01  | 10/884,866        | July 2, 2004       | Krieg et al.       |
| *C1039.70035US02  | 10/888,803        | July 9, 2004       | Krieg et al.       |
| *C1039.70048US03  | 10/831,647        | April 23, 2004     | Krieg et al.       |
| *C1039.70048US04  | 10/847,642        | May 15, 2004       | Krieg et al.       |
| *C1039.70048US05  | 10/877,407        | June 24, 2004      | Krieg et al.       |
| *C1039.70048US06  | 10/884,852        | July 2, 2004       | Krieg et al.       |
| *C1039.70048US07  | 10/888,785        | July 9, 2004       | Krieg et al.       |
| *C1039.70048US08  | 10/888,449        | July 9, 2004       | Krieg et al.       |
| *C1039.70048US09  | 10/894,657        | July 16, 2004      | Krieg et al.       |
| *C1039.70048US10  | 10/894,862        | July 16, 2004      | Krieg et al.       |
| *C1039.70048US11  | 10/928,762        | August 26, 2004    | Krieg et al.       |
| *C1039.70057US01  | 10/838,659        | May 3, 2004        | Davis et al.       |
| *C1039.70058US01  | 10/831,775        | April 23, 2004     | Davis et al.       |
| *C1039.70083US08  | 10/847,650        | May 15, 2004       | Krieg et al.       |
| *C1039.70083US09  | 10/888,885        | July 9, 2004       | Krieg et al.       |
| *C1039.70083US10  | 10/888,089        | July 9, 2004       | Krieg et al.       |
| *C1040.70006US01  | 10/888,886        | July 9, 2004       | McCluskie et al.   |
| *C1040.70012US00  | 10/644,267        | August 20, 2003    | Davis et al.       |
| *C1041.70002US01  | 10/877,369        | June 25, 2004      | Wagner et al.      |

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|-------------------|-------------------|--------------------|--------------------|
| *C1041.70002US02  | 10/876,965        | June 25, 2004      | Wagner et al.      |
| *C1041.70002US03  | 10/876,892        | June 25, 2004      | Wagner et al.      |
| *C1041.70005US01  | 10/811,226        | March 26, 2004     | Wagner et al.      |
| *C1041.70005US02  | 10/894,655        | July 16, 2004      | Wagner et al.      |
| *C1041.70016US01  | 10/884,372        | July 2, 2004       | Bauer et al.       |
| *C1041.70036US01  | 10/872,196        | June 18, 2004      | Lipford et al.     |

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding Foreign National Application.

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Mailing Date</u> | <u>Type of Communication</u> |
|-------------------|-------------------|---------------------|------------------------------|
| C1039.70006EP00   | EP 98 91 2919     | 12 August 2004      | European Search Report       |

### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Davis et al., Applicant*

By:



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Telephone: (617) 646-8000

Docket No.: C1039.70058US00  
Date: November 16, 2004  
**x11/12/04x**

|   |   |    |   |                                |                                   |
|---|---|----|---|--------------------------------|-----------------------------------|
| <p style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> |   |    |   | APPLICATION NO.: 10/023,909    | ATTY. DOCKET NO.: C1039.70058US00 |
|   |   |    |   | FILING DATE: December 18, 2001 | CONFIRMATION NO.: 8458            |
|   |   |    |   | APPLICANT: Davis et al.        |                                   |
|   |   |    |   | GROUP ART UNIT: 1648           | EXAMINER: Jeffery S. Parkin       |
| Sheet   | 1 | of | 3 |                                |                                   |

**U.S. PATENT DOCUMENTS**

| Examiner's Initials | Cite No. | U.S. Patent Document |           | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document<br>MM-DD-YYYY |
|---------------------|----------|----------------------|-----------|---|---|
|                     |          | Number               | Kind Code |   |   |
|                     | A52      | 4,578,269            |           | Morein  | 03-25-1986  |
|                     | A53      | 4,981,684            |           | MacKenzie et al.                                | 01-01-1991  |
|                     | A54      | 5,178,860            |           | MacKenzie et al.                                | 01-12-1993  |
|                     | A55      | 5,679,354            |           | Morein et al.                                   | 10-21-1997  |
|                     | A56      | 6,027,732            |           | Morein et al.                                   | 02-22-2000  |
|                     | A57      | 6,544,518            | B1        | Friede et al.                                   | 04-08-2003  |
|                     | A58      | 6,558,670            | B1        | Friede et al.                                   | 05-06-2003  |
|                     | A59      | 6,727,230            | B1        | Hutcherson et al.                               | 04-27-2004  |
|                     | A60      | 2001-0044416         | A1        | McCluskie et al.                                | 11-22-2001  |
|                     | A61      | 2002-0064515         | A1        | Krieg et al.                                    | 05-30-2002  |
|                     | A62      | 2002-0091097         | A1        | Bratzler et al.                                 | 07-11-2002  |
|                     | A63      | 2002-0164341         | A1        | Davis et al.                                    | 11-07-2002  |
|                     | A64      | 2002-0165178         | A1        | Schetter et al.                                 | 11-07-2002  |
|                     | A65      | 2002-0198165         | A1        | Bratzler et al.                                 | 12-26-2002  |
|                     | A66      | 2003-0026782         | A1        | Krieg et al.                                    | 02-06-2003  |
|                     | A67      | 2003-0026801         | A1        | Weiner et al.                                   | 02-06-2003  |
|                     | A68      | 2003-0050261         | A1        | Krieg et al.                                    | 03-13-2003  |
|                     | A69      | 2003-0050268         | A1        | Krieg et al.                                    | 03-13-2003  |
|                     | A70      | 2003-0055014         | A1        | Bratzler  | 03-20-2003  |
|                     | A71      | 2003-0087848         | A1        | Bratzler et al.                                 | 05-08-2003  |
|                     | A72      | 2003-0091599         | A1        | Davis et al.                                    | 05-15-2003  |
|                     | A73      | 2003-0100527         | A1        | Krieg et al.                                    | 05-29-2003  |
|                     | A74      | 2003-0104523         | A1        | Bauer et al.                                    | 06-05-2003  |
|                     | A75      | 2003-0139364         | A1        | Krieg et al.                                    | 07-24-2003  |
|                     | A76      | 2003-0148316         | A1        | Lipford et al.                                  | 08-07-2003  |
|                     | A77      | 2003-0148976         | A1        | Krieg et al.                                    | 08-07-2003  |
|                     | A78      | 2003-0166001         | A1        | Lipford   | 09-04-2003  |
|                     | A79      | 2003-0181406         | A1        | Schetter et al.                                 | 09-25-2003  |
|                     | A80      | 2003-0191079         | A1        | Krieg et al.                                    | 10-09-2003  |
|                     | A81      | 2003-0212026         | A1        | Krieg et al.                                    | 11-13-2003  |
|                     | A82      | 2003-0224010         | A1        | Davis et al.                                    | 12-04-2003  |
|                     | A83      | 2003-0232074         | A1        | Lipford et al.                                  | 12-18-2003  |
|                     | A84      | 2004-0009944         | A1        | Tam et al.                                      | 01-15-2004  |
|                     | A85      | 2004-0009949         | A1        | Krieg   | 01-15-2004  |
|                     | A86      | 2004-0030118         | A1        | Wagner et al.                                   | 02-12-2004  |
|                     | A87      | 2004-0038922         | A1        | Haensler et al.                                 | 02-26-2004  |
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**NOV 18 2004**  
**U.S. PATENT AND TRADEMARK OFFICE**  
**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

|       |   |    |   |                                |                                   |
|-------|---|----|---|--------------------------------|-----------------------------------|
|       |   |    |   | APPLICATION NO.: 10/023,909    | ATTY. DOCKET NO.: C1039.70058US00 |
|       |   |    |   | FILING DATE: December 18, 2001 | CONFIRMATION NO.: 8458            |
|       |   |    |   | APPLICANT: Davis et al.        |                                   |
|       |   |    |   | GROUP ART UNIT: 1648           | EXAMINER: Jeffery S. Parkin       |
| Sheet | 2 | of | 3 |                                |                                   |

|      |              |    |                 |            |
|------|--------------|----|-----------------|------------|
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| A94  | 2004-0131628 | A1 | Bratzler et al. | 07-08-2004 |
| A95  | 2004-0132685 | A1 | Krieg et al.    | 07-08-2004 |
| A96  | 2004-0142469 | A1 | Krieg et al.    | 07-22-2004 |
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| A98  | 2004-0147468 | A1 | Krieg et al.    | 07-29-2004 |
| A99  | 2004-0152649 | A1 | Krieg           | 08-05-2004 |
| A100 | 2004-0152656 | A1 | Krieg et al.    | 08-05-2004 |
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| A102 | 2004-0162258 | A1 | Krieg et al.    | 08-19-2004 |
| A103 | 2004-0162262 | A1 | Krieg et al.    | 08-19-2004 |
| A104 | 2004-0167089 | A1 | Krieg et al.    | 08-26-2004 |
| A105 | 2004-0171150 | A1 | Krieg et al.    | 09-02-2004 |
| A106 | 2004-0171571 | A1 | Krieg et al.    | 09-02-2004 |
| A107 | 2004-0181045 | A1 | Krieg et al.    | 09-16-2004 |
| A108 | 2004-0198688 | A1 | Krieg et al.    | 10-07-2004 |

#### FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Foreign Patent Document |             |           | Name of Patentee or Applicant of Cited Document<br>(not necessary) | Date of Publication of Cited Document<br>MM-DD-YYYY | Translation (Y/N) |
|---------------------|----------|-------------------------|-------------|-----------|--|---|-------------------|
|                     |          | Office/<br>Country      | Number      | Kind Code |  |   |                   |
|                     | B15      | EP                      | 0 773 295   | A2        | Ottawa Civic Hospital  | 05-14-1997  |                   |
|                     | B16      | WO                      | 98/52962    | A1        | Merck & Co., Inc.  | 11-26-1998  |                   |
|                     | B17      | WO                      | 99/56755    | A1        | University of Iowa Research Foundation                             | 11-11-1999  |                   |
|                     | B18      | WO                      | 00/09159    | A1        | Aquila Biopharmaceuticals, Inc.                                    | 02-24-2000  |                   |
|                     | B19      | WO                      | 00/15256    | A2        | Pasteur Merieux Serums et Vaccins                                  | 03-23-2000  | Y - Abstract Only |
|                     | B20      | WO                      | 00/23105    | A2        | Smithkline Beecham Biologicals S.A.                                | 04-27-2000  |                   |
|                     | B21      | WO                      | 00/46365    | A1        | Virginia Commonwealth University                                   | 08-10-2000  |                   |
|                     | B22      | WO                      | 00/62800    | A2        | Smithkline Beecham Biologicals S.A.                                | 10-26-2000  |                   |
|                     | B23      | WO                      | 02/28428    | A2        | Aventis Pasteur  | 04-11-2002  | Y - Abstract Only |
|                     | B24      | WO                      | 03/026688   | A1        | Pharmaderm Laboratories, Ltd.                                      | 04-03-2003  |                   |
|                     | B25      | WO                      | 2004/007743 | A2        | Coley Pharmaceutical GMBH  | 01-22-2004  |                   |
|                     | B26      | WO                      | 2004/039829 | A2        | Coley Pharmaceutical Group, Ltd.                                   | 05-13-2004  |                   |

|   |  |                                    |  |
|---|--|------------------------------------|--|
| <b>FORM PTO-1449/A and B (Modified)</b><br><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> |  |                                    |  |
| <b>NOV 18 2004</b><br><b>U.S. PATENT AND TRADEMARK OFFICE</b>                                   |  |                                    |  |
| <b>Sheet 3 of 3</b>   |  | <b>APPLICATION NO.:</b> 10/023,909 | <b>ATTY. DOCKET NO.:</b> C1039.70058US00 |
| <b>FILING DATE:</b> December 18, 2001   |  | <b>CONFIRMATION NO.:</b> 8458      |  |
| <b>APPLICANT:</b> Davis et al.  |  |                                    |  |
| <b>GROUP ART UNIT:</b> 1648   |  | <b>EXAMINER:</b> Jeffery S. Parkin |  |

**OTHER ART – NON PATENT LITERATURE DOCUMENTS**

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.  | Translation (Y/N) |
|---------------------|---------|--|-------------------|
|                     | C14     | DASS et al., Immunostimulatory activity of cationic-lipid-nucleic-acid complexes against cancer. <i>J Cancer Res Clin Oncol.</i> 2002 Apr;128(4):177-81. Epub 2002 Feb 23. Review. Abstract Only.  |                   |
|                     | C15     | O'HAGAN et al., Recent developments in adjuvants for vaccines against infectious diseases. <i>Biomol Eng.</i> 2001 Oct 15;18(3):69-85. Review. Abstract Only.  |                   |
|                     | C16     | O'HAGAN et al., Recent developments in vaccine delivery systems. <i>Curr Drug Targets Infect Disord.</i> 2001 Nov;1(3):273-86. Review. Abstract Only.  |                   |
|                     | C17     | McCLUSKIE et al., Mucosal immunization of mice using CpG DNA and/or mutants of the heat-labile enterotoxin of <i>Escherichia coli</i> as adjuvants. <i>Vaccine.</i> 2001 Jun 14;19(27):3759-68.  |                   |
|                     | C18     | RAZ et al., Potential role of immunostimulatory DNA sequences (ISS) in genetic immunization and autoimmunity. American College of Rheumatology 60th National Scientific meeting and Association of Rheumatology Health Professional 31st National Scientific meeting, Orlando, Florida, October 18-22, 1996. Abstracts. <i>Arthritis Rheum.</i> 1996 Sep;39(9 Suppl): 615. |                   |
|                     | C19     | SCHIRMBECK et al., Antigenic epitopes fused to cationic peptide bound to oligonucleotides facilitate Toll-like receptor 9-dependent, but CD4+ T cell help-independent, priming of CD8+ T cells. <i>J Immunol.</i> 2003 Nov 15;171(10):5198-207.  |                   |
|                     | C20     | SINGH et al., Recent advances in veterinary vaccine adjuvants. <i>Int J Parasitol.</i> 2003 May;33(5-6):469-78. Review. Abstract Only.   |                   |
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|                     | C22     | SINGH et al., Advances in vaccine adjuvants. <i>Nat Biotechnol.</i> 1999 Nov;17(11):1075-81. Review.   |                   |
|                     | C23     | SJOLANDER et al., Kinetics, localization and isotype profile of antibody responses to immune stimulating complexes (iscoms) containing human influenza virus envelope glycoproteins. <i>Scand J Immunol.</i> 1996 Feb;43(2):164-72.  |                   |
|                     | C24     | SJOLANDER et al., Iscoms containing purified Quillaja saponins upregulate both Th1-like and Th2-like immune responses. <i>Cell Immunol.</i> 1997 Apr 10;177(1):69-76.  |                   |
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|           |                  |
|-----------|------------------|
| EXAMINER: | DATE CONSIDERED: |
|-----------|------------------|

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]